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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,383	02/15/2001	John C. Voellmicke	DEP0468	3939

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EXAMINER

LEWIS, RALPH A

ART UNIT PAPER NUMBER

3732

DATE MAILED: 02/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/784,383

Applicant(s)
Voellmicke et al

Examiner
Ralph Lewis

Art Unit
3732



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 3, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 and 100 is/are pending in the application.
- 4a) Of the above, claim(s) 8, 42, 43, and 55-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-41, 44-53, 59-84, and 100 is/are rejected.
- 7) ☒ Claim(s) 54 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9 6) ☐ Other:

Art Unit: 3732

Restriction Requirement

Applicant's Election without traverse of a device for injecting bone cement with lever mechanism is acknowledged. The cancellation of claims directed to the composition is noted. Claims 8, 42 and 43 identified by applicant as being directed to a non-elected species are withdrawn from further consideration. Additionally, claims 55-58 are directed to nonelected embodiments of the device having reservoir mixing disks/blades and have been withdrawn from further consideration.

Inventorship

Applicant's request for changing the inventorship of the application under 37 CAR 1.48(b) is acknowledged. It would be of assistance to the Office if applicant would request the change in a separate paper.

Rejections based on 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 65-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 3732

Claim 6, setting forth an angle of 30 degrees contradicts the parent claim which requires a “substantially linear” arrangement.

In claim 65, line 1, there is no antecedent basis for “the integral means.”

Rejections based on Prior Art

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 9-31, 35, 36, 38-41, 44-53, 59-61, 63, 68-81, 84 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tolson (6,217,581 B1) in view of Scales (4,405,249) and Jaques (1,894,274).

Tolson discloses a bone cement injection device for injecting bone cement under high pressure into a bone cavity that includes a levered “high pressure, manually operated, hydraulic action gun 20 widely used for greasing automobiles” (column ³~~2~~, lines 43-45). Tolson does not explicitly disclose that the injection device is sterile, however, one of ordinary skill in the art would readily recognize that surgical devices are routinely sterilized so as to help prevent infections. Scales (column 3, lines 3-7; column 4, lines 64-68) teaches that such bone cement injection devices are sterile/sterilized to prevent infection. To have sterilized the Tolson injection

Art Unit: 3732

device 20 so as to help prevent infections would have been routine and obvious to one of ordinary skill in the art. Additionally, Tolson doesn't explicitly disclose a two chambered device with a reservoir and an injection chamber, but from the Figures illustrating the outside of the device it certainly appears to have such features. Moreover, Jacques is cited as disclosing a typical prior art levered automotive lubricating gun having a reservoir chamber 1 with exit opening 45, injection chamber 50, entry opening 44, and impermeable first piston 49. To have used a sterilized prior art lubricating gun as the high pressure injection gun 20 disclosed by Tolson would have been obvious to one of ordinary skill in the art in light of Tolson's Figures showing a very similar gun and disclosure that the gun may be those typically found in the automotive lubricating art.

In regard to claims 10 and 11, the specific volumes claimed would have been obvious to one of ordinary skill in the art as a matter of routine design. In regard to claim 17, note shaft 49 of Jaques. In regard to claim 18, note lever 52 of Jaques. In regard to claims 38-41, the specific numerical values claimed would have been obvious to one of ordinary skill in the art as a matter of routine design. In regard to claim 50, note compression spring 34 of Jacques. In regard to claim 59, note check valve 55, 56 of Jacques.

Claims 1-6, 9-41, 44-53, 59-81, 84 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tolson (6,217,581 B1) in view of Scales (4,405,249) and Stamper (4,168,787).

Art Unit: 3732

Tolson discloses a bone cement injection device for injecting bone cement under high pressure into a bone cavity that includes a levered “high pressure, manually operated, hydraulic action gun 20 widely used for greasing automobiles” (column 2, lines 43-45). Tolson does not explicitly disclose that the injection device is sterile, however, one of ordinary skill in the art would readily recognize that surgical devices are routinely sterilized so as to help prevent infections. Scales (column 3, lines 3-7; column 4, lines 64-68) teaches that such bone cement injection devices are sterile/sterilized to prevent infection. To have sterilized the Tolson injection device 20 so as to help prevent infections would have been routine and obvious to one of ordinary skill in the art. Additionally, Tolson doesn’t explicitly disclose a two chambered device with a reservoir and an injection chamber, but from the Figures illustrating the outside of the device it certainly appears to have such features. Moreover, Stamper is cited as disclosing a typical prior art levered automotive lubricating gun having a reservoir chamber 21 with exit opening 42, injection chamber 23, entry opening 44, and impermeable first piston 49. To have used a sterilized Stamper prior art lubricating gun as the high pressure injection gun 20 disclosed by Tolson would have been obvious to one of ordinary skill in the art in light of Tolson’s Figures showing a very similar gun and disclosure that the gun may be those typically found in the automotive lubricating art.

In regard to claims 10 and 11, the specific volumes claimed would have been obvious to one of ordinary skill in the art as a matter of routine design. In regard to claim 17, note shaft 24 of Stamper. In regard to claim 18, note lever 27 of Stamper. In regard to claims 38-41, the

Art Unit: 3732

specific numerical values claimed would have been obvious to one of ordinary skill in the art as a matter of routine design. In regard to claims 32, 33 and 37, note reservoir check valve 36 of Stamper. In regard to claim 34, note flow restrictor flap valve 48 comprised of a slitted 52 sheet. In regard to claim 50, note compression spring 19 of Stamper. In regard to claim 59, note check valve 55, 56 of Jacques.

Claims 1-6, 9-31, 35, 36, 38-41, 44-53, 59-61, 63, 68-81, 84 and 100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tolson (6,217,581 B1) in view of Scales (4,405,249) and Jaques (1,894,274) as applied above with respect to claim and in further view of Phillips et al (4,717,383), Draenert (4,671,263) and Hauke et al (5,551,778).

The Jacques high pressure injector lacks the claimed o-ring on first piston 49. O-rings are conventional on the pistons of high pressure injectors as evidenced by Phillips et al (note piston 12 with o-rings), Draenert (Figure 3, o-rings 52 on piston 50) and Hauke et al (Figure 7, piston 12 with o-ring) to improve the seal between the piston and the chamber. To have provided the Jacques piston 49 with an o-ring to improve the seal with the chamber would have been obvious to one of ordinary skill in the art.

Art Unit: 3732

Allowable Subject Matter


Claim 54 is objected to as being dependent on a rejected base claim but would be allowable if rewritten in independent form to include all of the limitations of the claims from which it depends..

Prior Art

Applicant's information disclosure statement of August 06, 2002 has been considered and an initialed copy enclosed herewith. Applicant is encouraged to cite only those references reasonably relevant to the patentability of the claimed invention.

Mikhail (5,718,707), Tolson (6,402,758) and Rickard et al (6,439,439) are made of record.

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(703) 308-0770**. Fax (703) 872-9302. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Kevin Shaver, can be reached at (703) 308-2582.


Ralph A. Lewis
Primary Examiner
Au3732

R.Lewis
January 14, 2003